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| APPLICATION NO.        | FILING DATE                                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|---------------------------------------------|----------------------|---------------------|------------------|
| 10/692,996             | 10/24/2003                                  | Jay Prabhakar Gore   | 3220-73780          | 9342             |
|                        | 7590 01/27/201 <sup>.</sup><br>HORNBURG LLP | EXAMINER             |                     |                  |
| 11 SOUTH ME            |                                             | GAKH, YELENA G       |                     |                  |
| INDIANAPOLIS, IN 46204 |                                             |                      | ART UNIT            | PAPER NUMBER     |
|                        |                                             |                      | 1797                |                  |
|                        |                                             |                      |                     |                  |
|                        |                                             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                        |                                             |                      | 01/27/2010          | ELECTRONIC       |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Application No.                                                                                                                                                            | Applicant(s)                                                               |  |  |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 10/692,996                                                                                                                                                                 | GORE ET AL.                                                                |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                             | Examiner                                                                                                                                                                   | Art Unit                                                                   |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Yelena G. Gakh, Ph.D.                                                                                                                                                      | 1797                                                                       |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                            |                                                                            |  |  |
| A SHO WHIC - Exter after - If NO - Failur Any r                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | ORTENED STATUTORY PERIOD FOR REPLEHEVER IS LONGER, FROM THE MAILING Ensions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by statute the polyreceived by the Office later than three months after the mailing adparent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION .136(a). In no event, however, may a reply be timed will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                            |                                                                            |  |  |
| <ol> <li>Responsive to communication(s) filed on <u>07 October 2009</u>.</li> <li>This action is <b>FINAL</b>. 2b) This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                            |                                                                            |  |  |
| Dispositi                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | on of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                            |                                                                            |  |  |
| 5)□<br>6)⊠<br>7)□<br>8)□                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Claim(s) 1-5,11,16-23 and 25-69 is/are pendida) Of the above claim(s) is/are withdrace Claim(s) is/are allowed.  Claim(s) 1-5,11,16-23 and 25-69 is/are rejected claim(s) is/are objected to.  Claim(s) are subject to restriction and/on Papers                                                                                                                                                                                                                  | awn from consideration.                                                                                                                                                    |                                                                            |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                            |                                                                            |  |  |
| Priority u                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ınder 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                            |                                                                            |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                            |                                                                            |  |  |
| 2) Notic<br>3) Inform                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date                                                                                                                                                                                                                                                                                                                  | 4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:                                                                                              | nte                                                                        |  |  |

Art Unit: 1797

#### **DETAILED ACTION**

1. Amendment to claim 57 filed on 10/07/09 is acknowledged. Claims 1-5, 11, 16-23 and 25-69 are pending in the application.

The Terminal Disclaimer filed on 10/07/09 is disapproved.

### Response to Amendment

2. Upon reading the Applicants' remarks and rereading the specification the examiner came to the conclusion that there was much confusion on examiner's side regarding understanding of the essence of the invention, as well as misunderstanding between the Applicants and the examiner. In light of these findings the examiner at present withdraws all rejections, except for rejections under 112, sec paragraph, and establishes objection to the specification with imposing questions which the examiner has regarding the invention disclosure. The examiner hopes that these questions will clarify the Applicants' invention and position so that the examiner can respond more efficiently to the Applicants remarks and/or amendments to the present office action.

#### **Specification**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as not containing "a written description of the invention... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same".

In particular, the specification discloses detecting a "post-absorbance" signal ([0011]). The examiner is not sure, what might be a "post-absorbance" signal. Detected signal can be either transmitted, reflected, or scattered, which are all can be considered "post-absorbance" signals, but all of which require different modes of detection and equipment. Furthermore, in the same paragraph the signals are disclosed as being modulated for the incident light, and also for

Art Unit: 1797

detection of modulated signals compared to unmodulated signals, which makes it unclear, as to how modulation occurs, and what is in fact modulated - the incident signals, or detected signals.

Furthermore, in paragraph [0012] the disclosed embodiment comprises "generating an electrical signal in response to detecting the modulated radiation". At the same time the paragraphs discloses "modulating incident signal". It is confusing, as to which signal is in fact being modulated - the one that is incident, or the one that is being detected. Furthermore, it is not clear, what does it mean "generating an electrical signal in response to detecting the modulated radiation"? Is this an active step of generating an electrical signal, or this is *transforming* optical signal into electrical signal using photodiodes?

The expression, which is used through the specification ""a detector for detecting radiation from the glucose absorbance bands and the reference band after the radiation is absorbed by the sample and then generating an electrical signal in response to detecting the modulated radiation" is very confusing. The examiner cannot interpret this in a senseful manner.

The examiner believes that what is disclosed is the method of measuring the glucose level by mid-IR spectrometry using broadband source with filtering glucose absorbency signals in mid-infrared region using optical filters, detecting optical transmitted signals and converting them into electrical signals, using the reference signal in the range where not glucose signals are present and applying linear regression analysis for obtaining glucose concentration using calibration samples.

Such examiner's interpretation raises the questions as to what different embodiments are disclosed in the specification, how they differ from each other, and what is the major distinction of the claimed invention from the prior art, which uses FTIR detection in mid-IR in combination with near-IR which utilizes algorithms for calculating the concentration of glucose.

The examiner will very much appreciate the Applicants' response and possible interview, which will accelerate the prosecution of the case.

#### Claim Objections

4. Claim 17 is objected to because of the following informalities: it recites "to give a measure the concentration", which is grammatically correct. Appropriate correction is required.

Art Unit: 1797

## Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 11, 16-23 and 25-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are written in the same unclear language as the specification and thus reflect the same issues, which were imposed for the specification. Clarification of the different embodiments and the method steps are respectfully requested.

#### Response to Arguments

7. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Y. Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/ Primary Examiner, Art Unit 1797

1/19/2010